## PROFESSIONAL HEARING HEALTH CARE

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October 23, 2000

Honorable Donna Shalala Secretary of Health and Human Services 200 Independence Avenue, SW Room 615F Washington, DC 20201

Dear Secretary Shalala,

As a small business owner and hearing health care provider, I am writing regarding proposed regulations affecting hearing instruments.

I am very concerned with reports which the Food and Drug Administration has sent to you regarding the revision of current regulations governing the dispensing of hearing instruments in this country. Said proposal would dramatically increase the cost of hearing health care services and restrict access to hearing health care providers. Please stop and carefully consider the impact this proposed rule will have on the nation's hearing impaired and on small business hearing instrument specialists everywhere. In particular, please ensure that any proposed rule meets the obligations of the Small Business Regulatory Enforcement Fairness Act.

Hearing impairment is a major health care concern. Please don't let the FDA put forth their proposed rule that would impede access to needed hearing health care services for millions of Americans.

Sincerely

Roman E. Theisen

**Board Certified Hearing Instrument Specialist** 

WA Lic. #666

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Honorable Donna Shalala Secretary of Health and Human Services 200 Independence Avenue SW Room 6157 Washington, DC 20201

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